

## REMARKS

By the foregoing amendments the Substitute Specification has been amended to update the status of the patent application referred to on page 19 of the Substitute Specification and an abstract on a separate sheet has been provided. Claims 43 and 46-49 have been amended, claims 44 and 53 have been cancelled and new dependent claim 54 has been added. Thus, with entry of the amendments, claims 43, 46-49 and 54 are in the application.

Claims 43, 44 and 46-51 stand rejected in the outstanding Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,955,399 B2 as stated on page 3 of the Office Action. This rejection is hereby traversed and reconsideration thereof is respectfully requested in view of the above amendments to the claims by which the prosthetic foot and lower part of leg of the present invention has been more particularly defined to distinguish over the claims of U.S. Patent No. 7,955,399. In particular, it is noted that claims 1-6 of the patent do not disclose or render obvious the prosthetic foot and lower part of leg of the invention having a resilient leg portion attached at a lower end to a foot keel and including a plurality of elongated, upwardly extending, generally arcuately curved in the sagittal plane, resilient leaf spring type members which are both spaced apart intermediate their upper and lower ends and are coupled together at their upper and lower end portions, the members being anterior facing convexly curved at their lower ends forming an ankle joint area and extending upwardly above the ankle joint area in a substantially anterior facing convexly curve to a substantially oriented

upstanding upper end of the leg portion as recited in the application claims as amended.

Claims 43, 44 and 46-51 are provisionally rejected in the outstanding Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims of co-pending application no. 12/886,758 as stated on page 3 of the Office Action. This provisional rejection is hereby traversed and reconsideration thereof is respectfully requested because application no. 12/886,758 is a later-filed application than the present application. The claims in the present, earlier filed application should not be provisionally rejected based upon the claims in the later-filed application, but should be permitted to issue as a patent without a terminal disclaimer in accordance with MPEP § 804.

Claims 43, 44, 47-49 and 53 are rejected in the Office Action under 35 U.S.C. § 102(e) as being clearly anticipated by Christensen, U.S. 6,929,665 B2 as stated on pages 4 and 5 of the Office Action.

Claims 43, 44, 46-49 and 53 are further rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Atkinson, et al., U.S. 2002/0087216 A1 in view of either Allen, et al., U.S. 5,653,767 A or Christensen. The references are combined for the reasons and in the manner set forth on pages 5-8 of the Office Action.

These rejections are hereby traversed and reconsideration thereof is respectfully requested in view of the above amendments to the claims and the remarks set forth below.

Applicants thank the Examiner for the helpful remarks on page 7 of the outstanding Office Action suggesting that for differentiating the claimed

invention from the prior art, the claims must be distinguished from the prior art in terms of structure rather than function. Responsive to this helpful suggestion, by the above amendments the single independent claim, claim 43 as been amended to expressly refer to the prosthesis of the present invention as a prosthetic foot and lower part of leg. The foot keel of the prosthetic foot has been defined as extending in a longitudinal direction. The semi-rigid, resilient leg portion is now defined as being attached at a lower end of the leg portion to the foot keel. The expression "to form" in the claim has been changed to --forming-- in reference to the plurality of resilient members of the leg portion being anterior facing convexly curved at their lower ends "forming an ankle joint area of the prosthesis". Further, the claim as amended recites that the plurality of resilient members of the leg portion extend upwardly above the ankle joint area in a substantially anterior facing convexly curve to a substantially vertically oriented upstanding upper end of the leg portion.

The resilient members are also now claimed as leaf spring type members which are coupled together at their upper and lower end portions while being spaced apart intermediate the ends, whereby the substantially vertically oriented upper end portion of the semi-rigid resilient leg portion in response to amputee gait force is displaced in a substantially longitudinal direction. Support for these additional limitations is found in the specification, see for example, page 10, lines 21-28 of the Substitute Specification referring to the terminal end/upper end having improved horizontal linear velocity, e.g. displacement in a substantially longitudinal direction. See longitudinal direction A-A in Figure 5 as referred to on page 9, lines 13-14 of the

Substitute Specification. See also page 14, lines 10-14 of the Substitute Specification.

The cited references do not anticipate, 35 U.S.C. § 102, or render obvious 35 U.S.C. § 103, the prosthetic foot and lower part of leg as recited in the amended claims.

The patent to Christensen discloses a prosthetic foot with a resilient ankle, but does not include a prosthetic lower part of leg as in the present invention which extends upwardly above the ankle joint area in a substantially anterior facing convexly curve to a substantially vertically oriented upstanding upper end of the leg portion. Christensen also fails to disclose or suggest a semi-rigid, resilient leg portion which is attached at a lower end to a foot keel and includes a plurality of elongated, upwardly extending, generally arcuately curved in the sagittal plane, substantially vertically oriented, semi-rigid resilient leaf spring type members which are spaced apart in the sagittal plane intermediate in their upper and lower ends and which are coupled together at their upper and lower end portions, the members being anterior facing convexly curved at their lower ends forming an ankle joint area of the prosthesis and extending upwardly above the ankle joint area in a substantially anterior facing convexly curve to a substantially vertically upstanding upper end of the leg portion, whereby the substantially vertically oriented upper end portion of the leg portion in response to amputee gait force is displaced in a substantially longitudinal direction as disclosed and claimed by Applicants in the amended claims.

In Christensen, the ankle portion is an s-shaped profile. In the embodiment of Figure 6 the resilient members 112 and 518 are not connected

at their lower ends but merely spaced from either other by means of a energy transfer member 524. The resilient members 112 and 518 are also not attached at a lower end of the members to foot keel 114 in the embodiment of Figure 6. An object of Christensen is to provide a prosthetic foot with improved shock absorption or a softer heel, column 1, lines 55-56. The use of an s-shaped profile provides vertical shock absorption or cushioning as noted in column 2, lines 3-5. The improved dynamic response of the prosthetic foot and lower part of leg of the present invention wherein the substantially vertically oriented upper end portion of the semi-rigid resilient leg portion in response to amputee gait force is displaced in a substantially longitudinal direction, is not achieved in the prosthetic foot of Christensen. The claims as amended are not anticipated, 35 U.S.C. § 102(e) by Christensen.

The amended claims are also believed to patentably define, 35 U.S.C. § 103, over Atkinson, et al., alone or in combination with one or more of Allen, et al. and Christensen. Figures 11, 13, 14, 19 and 20 of Atkinson, et al. were referred to in the rejection as stated on pages 5-7 of the Office Action. The prosthetic walking system of Atkinson, et al. is straight above the ankle, 412 in Figure 11, for example, where a conventional straight pylon extends upwardly from the ankle. Atkinson, et al. do not have a structure which is anteriorly facing convexly curved above the ankle to a substantially vertically oriented upstanding upper end as recited in Applicants claims as amended.

The ankle in Atkinson is essentially c-shaped for moving vertically under loading wherein substantially parallel upper and lower legs of the c-shaped ankle move toward and away from one another by virtue of a weakened or more flexible interconnecting section joining the upper and lower

legs. Atkinson, et al. do not teach or suggest the use of a semi-rigid, resilient leg portion including a plurality of elongated, upwardly extending, generally arcuately curved in the sagittal plane, substantially vertically oriented, semi-rigid, resilient substantially leaf spring type members which are coupled at their upper and lower end portions and which are spaced apart in the sagittal plane intermediate their upper and lower ends and which are anterior facing convexly curved at their lower ends forming an ankle joint area of the prosthesis and which extend upwardly above the ankle joint area in a substantially anterior facing convexly curve to a substantially vertically oriented upstanding upper end of the leg portion as recited in the claims as amended.

Because of the weakened or more flexible interconnecting portion in the c-shaped ankle of Atkinson, et al., the predominant motion during amputee gait force is essentially vertical. In contrast, because of the features of the present invention as recited in claim 43 as amended, the substantially vertically oriented upper end portion of the semi-rigid resilient leg portion of the prosthesis in response to amputee gait force is displaced in a substantially longitudinal direction. This improves dynamic response of the prosthesis in gait as discussed in the application specification.

Christensen and the secondary reference to Allen, et al. do not provide for the aforementioned deficiencies of Atkinson, et al. The prosthetic foot of Allen et al. is fundamentally different from that disclosed and claimed by Applicants. In Allen, et al. there is no foot keel in combination with the resilient leg portion as disclosed and claimed by Applicants, which leg portion is attached at a lower end to the foot keel as recited in claim 43 as amended.

In Allen, et al., the upper end of his resilient leg portion is not substantially vertically oriented, it is horizontally oriented or substantially horizontally oriented with the leg portions laying down completely horizontal in response to amputee gait force. The resilient leg members in Allen, et al. are spaced apart in the frontal plane not in the sagittal plane. The arc limiter 50 in the embodiment in Figure 6 is not coupled to the heel extension spring as recited in the application claims as amended.

Applicants respectfully submit that the improved prosthetic foot and lower part of leg of the present invention as recited in the claims as amended provides unexpected biomechanical results as compared to Christensen, Atkinson, et al. and Allen, et al. The unexpected biomechanical result is rooted in the fact that the substantially vertically oriented upper end of the semi-rigid resilient leg portion in response to amputee gait forces is displaced in a substantially longitudinal direction. More specifically, in response to amputee heel loading force the anterior facing convexly curved lower ankle joint area of the prosthesis and the resilient leg portion extending upwardly of the ankle joint area in a substantially anterior facing convexly curve to the substantially vertically oriented upstanding upper end of the semi-rigid resilient leg portion, are compressed, which is resisted less than expansion, to store energy. When this stored energy is released the proximal end portions are displaced longitudinally forward. This upper portion longitudinal forward displacement replicates the biomechanical function of the human shank and anterior pre-tibial muscle function.

The anterior pre-tibial muscles are much smaller in size as compared to the posterior calf muscles. Once the upper end portion is displaced forward

the prosthetic foot and lower part of leg/shank are in static resting state, midstance of amputee gait for example. As the body's center of mass progresses forward of the ankle joint area, the ground reaction force (GRF) starts its forward transition to the toe of the prosthetic foot and shank. As this occurs the aforesaid plurality of semi-rigid members expand which is much more resisted than the previously described heel loading compression. Whereby, this expansion loading of the semi-rigid resilient members replicates the human shank posterior calf muscle function.

In comparison, Christensen, Atkinson, et al. and Allen et al. have structural form which includes a posterior facing convexly curve somewhere in their design which responds to the toe GRF by compressing. This compression characteristic is completely opposite of expansion and negatively effects the magnitude of ankle joint sagittal plane kinetic power which is created in gait as discussed in the application specification. Thus, providing that the plurality of resilient members of the resilient leg portion extend upwardly above the ankle joint area in a substantially anterior facing convexly curve to the substantially vertically oriented upstanding upper end of the semi-rigid resilient leg portion is a significant factor and a difference from the cited prior art which contributes to the unexpected biomechanical results of the present invention as compared with the prior art. In view of the differences as recited in the claims as amended, it is respectfully submitted that the claims as amended patentably define over the cited references under 35 U.S.C. § 102 and 103. Accordingly, reconsideration and allowance thereof is respectfully requested.



A Petition for Extension of Time is filed herewith to permit the timely filing of this Amendment within the one month extension of time from the end of the shortened statutory period set in the outstanding Office Action.

A Request for Continued Examination is filed herewith to inquire consideration of the above amendments to the claims.

Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 01-2135 (Case No. 183.39735AX9) and please credit any excess fees to such deposit account.

Respectfully submitted,

/Ronald J. Shore/ 

Ronald J. Shore

Registration No. 28,577

ANTONELLI, TERRY, STOUT & KRAUS, LLP

RJS/kmh